

Title: A Sign from the Heavens

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Description: Roger, who was diagnosed with schizophrenia 20 years ago, wants to enroll in an experimental drug study based on the recommendation of his psychic.

Headings: Decision-making Capacity, Assent, and Surrogate Permission; Decision-making capacity (competence), determination of; Mental health disorders, participants with (including addictive disorders and developmental disabilities)

Case Type: Decision making

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Twenty years ago, Roger was diagnosed with schizophrenia, paranoid type. Over the years he has undergone many types of treatment with varying degrees of success. Roger found that although the treatments reduced his symptoms, often the side effects were more than he could bear. So he would take himself off medication and his schizophrenic episodes would return. At times Roger is so worn out by frightening all-night psychotic episodes that he considers suicide; but he still resists going back on medication.

Lately Roger has been feeling a lot better. He hasn't had an episode in a month and his mind feels "clear". He has even been able to work on the next chapters of his mystery novel, which he had abandoned months ago when his episodes were particularly intense. Roger's mother, whom he visits regularly, notices his improvement and is delighted. However, they both know that it is only a matter of time before the symptoms return and the disorder consumes his life again.

Willing to try anything to avoid another episode, Roger decides to visit a psychic to get "advice from the heavens." His mother is not particularly bothered by Roger's visits to psychics. She's glad he's trying to find some source of hope. Upon visiting an astrologer he is advised to seek out an experimental drug and is assured that the "universe will grant him a miracle cure" through this new medicine. Roger leaves the astrologer and heads to the local diner to read the newspaper. On the back page he reads about a Phase II clinical trial of an antipsychotic agent that is enrolling adult patients with schizophrenia.

Roger immediately contacts the research director at the university-affiliated hospital. The researcher explains that this experimental drug is being tested for its efficacy and safety and might not improve his symptoms. The drug has shown modest success in previous trials, but has potentially severe side effects. Roger expresses extreme interest in participating.

The research protocol involves administering a short assessment of decision-making capacity to all potential participants who are interested in the project. Those who are deemed incompetent are either not allowed to participate, or need the permission of a legally authorized surrogate decision-maker in addition to providing their own assent. Among other things, the assessment explores understanding of the protocol, appreciation of risks and benefits, and the reasoning processes used to decide whether to enroll. The evaluator finds that Roger is not in a psychotic episode and that he understands the risks

and benefits extremely well. But he is concerned when Roger explains that he is certain he will receive benefits from the study, and that he decided to enroll because an astrologer instructed him to seek out this study.

Would you as the researcher, admit Roger into the study? Why or why not?